Veterinary Bone Graft – Package Insert & Instructions for Use

Freeze-Dried Osteoallograft® and Specialty Grafts

Freeze-Dried Storage & Handling

Storage: Room Temperature
Expiration: 5 years (see exp. date on package label)

VTS
Freeze-Dried
Irradiated

Instructions for Use

Circulator:

1. Remove the Transplant Record and peel pouch containing the graft from the outer box. Everything inside the peel pouch is considered sterile.
2. Inspect the pouch. If it is damaged, consider the graft unsterile.
3. Using sterile technique, peel the pouch open and present the sterile innermost vacuum-sealed pouch containing the graft to a sterile team member.
4. Complete the **Transplant Record, then** fax or return a copy to VTS and retain a copy for your patient records.

Sterile Team Member or Surgeon:

5. To access the graft, tear open the innermost pouch and remove the graft. If the graft is protected in a Tyvek packet, cut open the packet and place the graft into the vial (if provided) or a suitably sized basin for rehydration.
6. Obtain a few milliliters of blood and/or sterile physiologic solution (*e.g.*, buffered saline or other isotonic solution) to use for rehydration. Although not required, antibiotics may be added to the rehydration solution.
7. To rehydrate:
   - If in a syringe, inject a sufficient amount of blood and/or rehydration solution through the blue cap at the truncated end of the syringe.
   - If in a jar or other container, add sufficient blood and/or rehydration solution to minimally cover the graft.
   - Minimal to no waiting is required for rehydration of particulate grafts. Full rehydration of larger grafts may take 5-10 minutes, or longer, depending on size.
8. Aspirate or decant any excess liquid. If in a syringe, remove the blue cap & use the plunger handle to push the black stopper to dispense the graft into a basin or directly to the site (*be careful to retain the black stopper*). Combine graft with patient blood or bone marrow to provide access to osteoprogenitor cells and serologic factors that may facilitate clot formation and healing. The graft may also be mixed with autograft. If possible, ensure that grafts are implanted in a site with good vascular access.

Graft Description

VTS grafts are supplied as particulate grafts (**Osteoallograft®**) or as specialty grafts.

- **Osteoallograft®** is either demineralized bone matrix (DBM) alone, or a combination of DBM and cancellous bone chips. It is packaged in doses measured in cubic centimeters (*e.g.*, 1 cc or 3 cc) and supplied in various particle size ranges. There are no other carrier additives.
- **Specialty grafts** are made of cortical or cancellous bone and are available in varying shapes and sizes, including: blocks, rings, dowels, struts, whole bones, diaphyseal shaft sections, flexible membranes, and sponges, *etc.* Some specialty grafts are demineralized. There may be some slight natural biological variations in the structure (*e.g.*, density of the cancellous bone).

Specific applicable information about each individual graft (*e.g.,* graft type and preservation method, dose or dimensions, species of the donor, *etc.*) is found on the label affixed to the graft packaging. VTS grafts are packaged in a sealed moisture vapor barrier pouch and protected by an outer peel pouch layer.

Indications & Uses

Osteoallograft® or **Specialty grafts** may be used wherever a bone graft is needed. Bone graft is used in a wide variety of periodontic, orthopedic, neurosurgical and other reconstructive surgeries. It may be used by itself, or in combination with autograft, additives (such as PRP or bone marrow), bone graft substitutes, or other implants. **Whole bone** grafts or **bone sections** (diaphyseal cortical shaft sections) are typically used for segmental replacement. **Ossiflex® Bone Membranes** may be used wherever a flexible bone graft is needed. Flexible bone membranes integrate with the host tissue and may be used for guided tissue regeneration, cleft palate repair, occlusion of bony defects, or containing particulate graft material, *etc.*

For particulate **Osteoallograft®**, pack into the defect site and ensure it completely fills the space. **Specialty grafts** (*e.g.,* cortical blocks, sections, *etc.*) may be cut to fit the patient size requirements (use sterile irrigant to cool the graft if using a saw). All grafts should be implanted in a well-stabilized site. Demineralized sponge grafts may be compressed, if necessary. It may be advantageous to place particulate autograft or allograft at the graft-host junctions or in the medullary canal when using ring sections, segments and whole bone specialty grafts. Flexible bone membranes can hold sutures, but ensure that sutures are not placed too closely to the edges, because with significant stress they may tear through the membrane.

The packaging and dosages are intended for use in one patient on a single occasion only. The volume or type of graft necessary for any surgical procedure depends on surgeon preference and varies with the size & type of defect.

Contraindications and Precautions

Caution: Federal law restricts this device to sale by or on the order of a licensed veterinarian; it is not for use in human patients.

The tissue may not be sterilized or re-sterilized.

As with any bone autograft, bone allograft should not be implanted into a site with active or latent infection, as this may lead to resorption of the graft.

Tissue processing procedures, donor screening and tissue testing procedures are all designed to reduce the risk of infection or disease transmission. Even though rigorous

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Contraindications and Precautions (continued)

quality controls are in place to minimize the risk, as with all transplants or transfusions there may be some small risk of disease transmission. Adverse outcomes potentially attributable to the tissue must be reported promptly to VTS.

Please retain a copy of the Transplant Record for your patient files to facilitate contacting us and to enable tracing of tissues. If you have any comments or if there is any dissatisfaction with the graft or packaging at the time of implant, please notify us using the Comment section of the Transplant Record or by calling or reporting by e-mail through our website (see below).

Records, such as a log book, should be maintained for the purpose of tracing tissues to patients (*e.g.*, date of receipt, date of transplant, recipient identification, *etc.*).

Donor/Graft Suitability

This tissue has been determined to be suitable for implantation by Veterinary Transplant Services. All required infectious disease testing and screening has been completed, reviewed and found to be acceptable, negative or non-reactive. Owners and medical staff knowledgeable about the donor are interviewed about the donor's medical history. Additionally, all donors are screened for infectious diseases with nucleic acid tests (aka. PCR). These are extremely sensitive assays designed to identify the presence of infectious agents by amplification of their DNA or RNA.

Canine donors should have been vaccinated for at least for rabies, canine distemper, parvovirus, and hepatitis (adenovirus-2). If no record of vaccination, appropriate tissue samples must have been tested and the results found to be non-detectable with nucleic acid tests (*e.g.,* PCR) for these typical vaccine agents. Additionally blood or tissue samples are also tested using PCR and must be negative for *A. platys, A. phagocytophilium, E. canis, M. haemocanis, M. haematoparvum, Rickettsia spp., Leishmania spp., Babesia spp.,* and *Bartonella spp.*

Feline donors must have appropriate tissue samples tested with nucleic acid tests and the results found to be non-detectable for rabies (if not vaccinated already), *M. haemofelis, M. haemominutum, M. turicensis, Bartonella spp.*, Feline Leukemia Virus (FeLV), Feline Immunodeficiency Virus (FIV) and Feline Corona Virus.

Equine donors should have been vaccinated at least for Rabies and Tetanus (*Clostridium tetani*). If no record of vaccination, appropriate tissue samples must have been tested with PCR and the results found to be non-detectable for these agents. Blood samples drawn at the time of donation have tested negative for Equine Infectious Anemia and *Brucella abortus*. Additionally, blood and tissue samples obtained at the time of donation have been tested by PCR testing and found negative for: Eastern Equine Encephalitis (EEE), Western Equine Encephalitis (WEE), West Nile Virus (WNV), Equine Herpes Virus types 1 & 4 (EHV1, EHV4), Equne Protozoal Myeloencephalitis (EPM), Venezuelan Encephalitis (VEE), *Corynebacterium pseudotuberculosis* (aka. Pigeon Fever), Equine Viral Arteritis (EVA), Influenza A (H3N8), Streptococcus equi, Equine Rhinitis A and B Virus (ERAV, ERBV), *Neorickettsia risticii*-formerly known as *Ehrlichia* genus (aka. Potomac Horse Fever), and Piroplasmosis (*Babesia caballi and equi*).

Microbial assessments are performed at procurement, during processing and at packaging. All cultures are 14 day cultures for aerobes, anaerobes and yeast. Additionally, final-packaged grafts are gamma irradiated. Grafts are not released unless their final packaging irradiation documentation is acceptable.

Processing

All tissue grafts are collected aseptically and processed in a sterile, laminar airflow environment using procedures that are rigorously quality-controlled and designed to prevent contamination and cross-contamination. Grafts are processed with proprietary solutions that may include antibiotics, alcohols, hydrogen peroxide, acids, buffers, enzymes, and/or surfactants. Processing steps are designed to remove cellular elements and reduce immunogenicity while preserving osteoinductive proteins. Traces of processing agents may remain. Freeze-dried grafts are preserved using lyophilization to reduce the water content of the tissues and minimize structural changes to proteins. The grafts are packaged to prevent protein degradation from oxidation, and then gamma irradiated. Each irradiated graft receives an acceptable low dose of gamma radiation, which has been shown to reduce bioburden while retaining protein activity. There is an indicator label on the product packaging that turns from orange to red upon exposure to irradiation.

Storage & Handling

Freeze-dried bone graft can be stored for 5 years from the packaging date at ambient room temperature. Protect the packets from heating above 120°F (45°C) for more than 2 days. The expiration date is indicated on the individual label of each freeze-dried graft.

The packaging is designed to remain intact during the stated shelf life, and if unopened and undamaged will maintain the aseptic condition of the graft. Care should be taken to ensure that the packaging is not damaged prior to use. It is the responsibility of the clinician to maintain appropriate storage conditions prior to transplant. After the peel pouch has been opened, the graft should be maintained in aseptic conditions and the tissue should be implanted or otherwise discarded. If the tissue has been opened for more than 2 hours, it should be refrigerated in a sealed container to minimize the risk of inadvertent contamination. If it is not used within 6 hours it should be discarded.

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